

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

ACCEL-HYOSCINE Hyoscine Butylbromide Tablets Mfr. Std.

Read this carefully before you start taking **ACCEL-HYOSCINE**. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ACCEL-HYOSCINE**.

What are ACCEL-HYOSCINE tablets used for?

- For the relief of abdominal spasms (cramps), pain and discomfort in the:
 - stomach,
 - gut (intestines / bowel),
 - biliary tract.

How do ACCEL-HYOSCINE tablets work?

- Abdominal cramps (spasms) are caused by sudden, strong tightening of muscles.
- Relieves cramps (spasms), pain, discomfort by relaxing tight muscles of the:
 - stomach,
 - gut (intestines / bowel),
 - biliary tract.

What are the ingredients in ACCEL-HYOSCINE tablets?

Medicinal Ingredient: Hyoscine butylbromide.

Non-medicinal Ingredients: lactose monohydrate, lecithin (soya), macrogol, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, povidone, talc and titanium dioxide.

ACCEL-HYOSCINE comes in the following dosage form:

Tablets, 10 mg.

Do not use ACCEL-HYOSCINE tablets if you:

- are allergic to:
 - hyoscine butylbromide.
 - atropinics.
 - any of the ingredients in the product (see list in **What are the ingredients in ACCEL-HYOSCINE tablets**).
- have any of the below conditions:
 - muscle wasting disease (myasthenia gravis).
 - untreated high pressure inside of your eye (closed-angle glaucoma).

- narrowing parts of the gastrointestinal tract (stenosis).
- problems with urination due to prostate issues.
- your intestine stopped working or may be blocked;
 - Symptoms include:
 - severe abdominal pain with absence of stools,
 - nausea,
 - vomiting
 - enlarged bowel (megacolon).
- are pregnant, likely to get pregnant, or are breast-feeding.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ACCEL-HYOSCINE. Talk about any health conditions or problems you may have, including if you:

- are a man and have prostate problems
- are at risk of narrow angle glaucoma (high pressure in the eyes)
- are at risk of having problems with urinating due to a blockage
- are at a risk of tachyarrhythmia (high heart rate)
- have stomach acid backing up in your throat (reflux-esophagitis)
- have or at a risk of any blockage in your gastrointestinal tract. This includes your esophagus, stomach, intestines and anus.
- have inflamed bowels (e.g. ulcerative colitis).

Other warnings you should know about:

You should not be taking ACCEL-HYOSCINE daily for a long period of time. Your healthcare professional should investigate the cause of your stomach pain. Talk to your healthcare professional about how long you should be taking ACCEL-HYOSCINE.

If the following occurs after you take ACCEL-HYOSCINE, get medical help immediately:

- if you have severe and unexplained stomach pain that does not go away or gets worse
- if you have severe and unexplained stomach pain that occurs with other symptoms such as:
 - fever
 - nausea
 - vomiting
 - changes in bowel movements
 - abdominal tenderness
 - decreased blood pressure
 - fainting
 - blood in stool

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines. The following may interact with ACCEL-HYOSCINE:

- Amantadine, medicine used to prevent or treat certain flu infections (type A)
- Anticholinergics (e.g. ipratropium, atropine).
- Antihistamines, medicines used to treat allergies (e.g. diphenhydramine, hydroxyzine).
- Beta-adrenergic agents, medicines used to treat the symptoms of asthma, bronchitis, emphysema, and other lung diseases (e.g. salbutamol).
- Dopamine antagonists, medicines used for the prevention of vomiting (e.g. metoclopramide).
- Heart medications (e.g. disopyramide, quinidine).
- MAO inhibitors, medicines used to treat depression and mood disorders (e.g. moclobemide, selegiline, tranylcypromine, phenelzine).
- Tricyclic antidepressants, medicines used to treat anxiety or depression (e.g. amitriptyline, doxepin).

If you are taking antacids or adsorbent anti-diarrheals, your healthcare professional may tell you to take them at least 1 hour before taking ACCEL-HYOSCINE.

How to take ACCEL-HYOSCINE tablets:

Usual dose (Adults):

- Take 1 to 2 tablets per day. Do not take more than 6 tablets per day.
- In prolonged illness, your doctor may recommend taking one tablet 3 to 5 times a day. Do not take more than directed.
- Swallow tablets whole with a glass of water.

Overdose:

If you think you, or a person you are caring for, have taken too much ACCEL-HYOSCINE, contact a healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

In case a dose has been missed, take the next dose as scheduled. Do not double the dose.

What are the possible side effects from using ACCEL-HYOSCINE tablets?

This drug may sometimes cause:

- dry mouth.
- diarrhea.
- nausea.
- feeling hot and decreased sweating.
- increased heart rate.

- not being able to pass urine.
- increase fluid pressure inside of the eye.
- other rare side effects such as:
 - allergic reactions (skin rash and itching).
 - skin reactions (e.g. hives, rash, skin redness, itching).
 - rapid swelling of the skin and skin tissue (angioedema).
 - difficulty in breathing (usually in patients who suffer with asthma or allergy).

There have been very rare reports of severe, allergic reactions and severe allergic shock.

If you experience any of these effects which persist or become troublesome or any side effects not listed here, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature (15 - 30°C). Product is stable up to the labelled expiry.

Keep out of reach and sight of children.

If you want more information about ACCEL-HYOSCINE:

- Talk to your healthcare professional.
- Find the full Prescribing Information that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); or by contacting the sponsor, Accel Pharma Inc, by visiting www.accelpharma.com, or by calling **1-877-822-2235**.

This leaflet was prepared by Accel Pharma Inc.

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